

(iv) "Guidance Document for the Preparation of Premarket Notification (510(k)) Application for Orthopedic Devices," and

(v) "Guidance Document for Testing Non-articulating, 'Mechanically Locked' Modular Implant Components,"

(2) International Organization for Standardization's (ISO):

(i) ISO 5832-3:1996 "Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6-aluminum 4-vandium Alloy,"

(ii) ISO 5832-4:1996 "Implants for Surgery—Metallic Materials—Part 4: Cobalt-chromium-molybdenum casting alloy,"

(iii) ISO 5832-12:1996 "Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-chromium-molybdenum alloy,"

(iv) ISO 5833:1992 "Implants for Surgery—Acrylic Resin Cements,"

(v) ISO 5834-2:1998 "Implants for Surgery—Ultra-high Molecular Weight Polyethylene—Part 2: Moulded Forms,"

(vi) ISO 6018:1987 "Orthopaedic Implants—General Requirements for Marking, Packaging, and Labeling," and

(vii) ISO 9001:1994 "Quality Systems—Model for Quality Assurance in Design/Development, Production, Installation, and Servicing," and

(3) American Society for Testing and Materials':

(i) F 75-92 "Specification for Cast Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implant Material,"

(ii) F 648-98 "Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants,"

(iii) F 799-96 "Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants,"

(iv) F 1044-95 "Test Method for Shear Testing of Porous Metal Coatings,"

(v) F 1108-97 "Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants,"

(vi) F 1147-95 "Test Method for Tension Testing of Porous Metal,"

(vii) F 1378-97 "Standard Specification for Shoulder Prosthesis," and

(viii) F 1537-94 "Specification for Wrought Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants."

[52 FR 33702, Sept. 4, 1987, as amended at 65 FR 17148, Mar. 31, 2000]

§ 888.3670 Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.

(a) *Identification.* A shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a shoulder joint. The device limits movement in one or more planes. It has no linkage across-the-joint. This generic type of device includes prostheses that have a humeral component made of alloys such as cobalt-chromium-molybdenum (Co-Cr-Mo) and titanium-aluminum-vanadium (Ti-6Al-4V) alloys, and a glenoid resurfacing component made of ultra-high molecular weight polyethylene, or a combination of an articulating ultra-high molecular weight bearing surface fixed in a metal shell made of alloys such as Co-Cr-Mo and Ti-6Al-4V. The humeral component and glenoid backing have a porous coating made of, in the case of Co-Cr-Mo components, beads of the same alloy or commercially pure titanium powder, and in the case of Ti-6Al-4V components, beads or fibers of commercially pure titanium or Ti-6Al-4V alloy, or commercially pure titanium powder. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. This generic type of device is designed to achieve biological fixation to bone without the use of bone cement.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis."

[66 FR 12737, Feb. 28, 2001]